REMARKS

Claims 57-76 remain pending after amendment.

Claim Amendments

Claims 1-3, 15, 22, 24-26, 33, 42-52, and 56 are canceled, and rewritten (and reordered) as new claims 57-76. Claims 57-76 correspond to the previous pending claims as follows:

New claim(s)	*Corresponding Prior Claim(s)*
57	22
58-60	24-26
61-62	42-43
63-70	45-52
71-73	1-3
74	15
75	33
76	56

Further, new claim 71 combines the limitations of canceled claims 1 and 6. New claim 75 combines the limitations of canceled claims 33 and 37. Canceled independent claim 46 is rewritten as new dependent claim 64. No new matter is added by this amendment.

Status of Prosecution

Applicants note that a three-month period for suspension was requested upon the filing of the RCE on December 4, 2006. The Office Action issued on December 13, 2006 was thus premature. The Examiner was informed of this during a telephone interview of December 28, 2006, at which time the Examiner indicated that he would withdraw the Action of December 13, 2006 pending expiration of the suspension period. See the Interview Summary Record of December 28, 2006 filed by applicants.

However, as the Examiner apparently inadvertently failed to withdraw the noted Action, and as applicants are not believed to be prejudiced by such non-withdrawal, applicants respond herewith to the Action of December 13, 2006, and the comments of the Examiner present therein.

Allowable Subject Matter

Applicants acknowledge with appreciation the indication of allowable subject matter of claims 33, 37 and 56.

Applicants note that the Examiner, in the Office Action of November 2, 2005, indicated that claims 3, 6, 24-26, 42, 43 and 45-46 were allowable. This prior indication of allowable subject matter has not been expressly withdrawn by the Examiner. It is also noted that these claims are not presently rejected over the prior art of record. The subject

matter of claims 3, 6, 24-26, 33, 37, 42, 43, 45-46 and 56 is thus believed to be allowable. New claims 57-76 correspond to allowed claims 3, 6,24-26, 33, 37, 42, 43, 45-46 and 56.

This inconsistency notwithstanding, for the following reasons, applicants believe that all pending claims 57-76 are directed to allowable subject matter.

Rejection under 35 USC 112 (paragraph two)

Claims 1-3, 6, 15, 22, 24-26, 42, 43 and 45-55 stand rejected under 35 USC 112 (paragraph two) as not distinctly claiming the invention.

In support of the rejection, the Examiner takes the position that the recitation of "effective amount" is indefinite, as it is unclear "how much is 'an amount effective' to [treat] IBD i.e., 1%, 10%,1mg,10mg, etc." The Examiner further requests applicants to "Please amend the claims to recite a specific amount". This rejection is respectfully traversed.

Applicants initially note that rejected claim 1 (now claim 71) recites the administration of "an amount effective to treat IBD". Rejected claim 22 (now claim 57) recites the administration of "a therapeutic amount". In response, applicants submit that a person of ordinary skill in the art is provided with more than sufficient information and guidance in the specification in order to determine what would constitutes an effective or therapeutic amount of polysaccharide to treat IBD.

For example, one of ordinary skill in the art is provided with preferred ranges. See, for example, pages 7-9 and 11, as well as applicants' Examples, which disclose exemplary effective and/or therapeutic dosage amounts.

In addition, based on such teachings, it is entirely within the ability of one of ordinary skill in the art to determine what polysaccharide concentration would be suitable. In this connection, applicants note that the Examiner seeks to reject Claim 15 (now claim 74) under 35 USC 103(a) on the basis that it *would be within the skill of the ordinary worker to determine that a range of 400 to 2000 mg of polysaccharide would be effective to treat IBD.* Accordingly, the Examiner *concedes* it to be within the ability of the person of ordinary skill to calculate an "effective or therapeutic amount" to treat IBD.

In any event, each of claims 65, 66, 67, 68, 69, 70, 74. 75, or 76 (which each are directed to a specific concentration % or dosage amount) is believed to fully comply with the requirements of the statute in this regard, and should be found free of rejection under 35 USC 112 (paragraph two), in addition to the remaining claims (for the reasons noted above).

The rejection is accordingly without basis and should be withdrawn.

Rejection of Claims 1-2 and 22 under 35 USC 102(b)

Claims 1-2 and 22 stand rejected under 35 USC 102(b) as being anticipated by Day. This rejection is respectfully traversed.

Applicants again note that claims 1, 2, 9 and 27-28 in an Official Action of April 25, 2001 were previously rejected under 35 USC 102(b) as being anticipated by Day '136, which corresponds to Day '522. This prior rejection was withdrawn by the Examiner.

Applicants thus again question the basis for the rejection of claims 1-2 over Day '522, and request clarification by the Examiner.

Applicants have nonetheless incorporated the limitations of previously-allowed claim 6 into claim 1. Claims 1 and 2 (now claims 71 and 72) are accordingly believed to be directed to allowable subject matter.

New claim 71 requires that the DRO composition be in the form of an enteric coated dosage form. Day does not disclose or suggest an enteric coated dosage form and, thus, the subject matter of new claim 71 is allowable over Day.

With regard to rejected claim 22 (now claim 57), Day discloses treatments for irritable bowel syndrome ("IBS"), and not inflammatory bowel disease ("IBD"). The Examiner's attention is drawn to the comments filed on August 16, 2005 regarding the distinctions between IBS and IBD. In addition to those comments, the Examiner should note that the identity of conventional drugs used to treat IBS and IBD further emphasizes the fact that the conditions are entirely different. For example, IBD is usually treated with steroids, anti-inflammatory agents, immunosuppressants, anti-TNF-alpha therapies and antibiotics. In stark contrast, IBS is usually treated with anxiolytics, anti-depressants, anti-spasmotics, abdominal muscle relaxants and anti-diarrheal agents. The person of ordinary skill would appreciate that it is far from obvious that a treatment of IBS would also be suitable to treat IBD.

In any event, Day does not disclose or suggest that the polysaccharide may constitute the sole therapeutic agent when the composition is administered singly. First,

Day does not disclose administration of a hydrophilic polymer without co-administration of an anion-binding polymer. In contrast, Day actually discloses that "*It is only the combination of anion-binding polymer and hydrophilic polymer which is effective in preventing and relieving symptoms of (IBS)...*" (see column 6, lines 26/29). Secondly, where Day does disclose the administration of a single polymer (see column 4, lines 57/60), that polymer *must* have both anion-binding properties and hydrophilic properties. Neither xanthan gum nor HPMC has anion-binding properties. In contrast, xanthan gum has **cation**-binding properties and HPMC has **non-ionic** binding properties. Thus, neither of the polysaccharides of the present invention satisfies the anion-binding requirement of the polymers in Day.

Applicants question whether the Examiner might be misinterpreting part of the disclosure in Day. Day discloses that "*The invention...comprises the following, inter alia, singly or in combination...*" (see column 4, lines 3/4). This sentence does not mean that, where the anion-binding polymer and the hydrophilic polymer are separate polymers, one may be administered without the other (i.e. "singly"). In contrast, this sentence means that the invention incorporates one or more of the features in the following list in any combination. Each of the features in the list either requires the presence of the combination of separate anion-binding and hydrophilic polymers or requires the presence of a single polymer having both properties, e.g. chitosan.

In view of the above, the rejection is without basis and should be withdrawn.

Rejection of Claims 27 and 38 under 35 USC 102(e)

Claims 27 and 38 stand rejected under 35 USC 102(e) as being anticipated by Sachetto. This rejection is respectfully traversed.

In response, claims 27 and 28 are canceled. As a result, the rejection is moot and should be withdrawn.

Rejection of Claim 15 under 35 USC 103(a)

Claim 15 stands rejected under 35 USC 103(a) as being unpatentable over Day. This rejection is respectfully traversed.

In response, claim 15 (now claim 74) depends from claim 71. As claim 71 recites the limitations of previously-allowed claim 6, claim 71 and those claims depending therefrom (including claim 74) are thus similarly believed to be allowable.

The rejection is thus moot and should be withdrawn.

Rejection of claim 39 under 35 USC 103(a)

Claim 39 stands rejected under 35 USC 103(a) as being unpatentable over Sachetto '310. This rejection is respectfully traversed.

In response, claim 39 is canceled. The rejection is thus moot and should be withdrawn.

In view of the above, the application is believed to be in condition for allowance. An early indication of same earnestly is solicited.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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